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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,740	01/22/2007	Patrick Schweizer	MAIWAM7.005APC	1910

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EXAMINER	
IBRAHIM, MEDINA AHMED	
ART UNIT	**PAPER NUMBER**
1638	

NOTIFICATION DATE	DELIVERY MODE
05/02/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/574,740	SCHWEIZER ET AL.	
	Examiner	Art Unit	
	MEDINA A. IBRAHIM	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18 and 21-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-18 and 21-32* is/are rejected.

7)☒ Claim(s) *2* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 April 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/05/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-18 and 21-32 are pending and are examined.

Sequence Listing

The specification is objected to for reciting a sequence with no sequence identifier, SEQ ID NO. For example, the sequences on pages 19-20, and 22 lack sequence identifiers. Nucleotide and /or amino acid sequences as used in §1.821 through 1.825 are interpreted to mean unbranched sequence of four or more amino acids or an unbranched sequence of ten or more nucleotides in patent applications. The 37 CFR 1.821(d) requires the use of the assigned sequence identifier in all instances where the description or claims of a patent application discuss sequences regardless of whether a given sequence is also embedded in the text of the description or claims of an application. Applicant is respectfully requested to check the specification for sequences and identify the sequences by SEQ ID NO: or to submit a new Sequence Listing, which comprises said sequences.

The disclosure is also objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
    (1) Field of the Invention.
    (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

The instant is objected to for lacking parts (b) to (h).

Content of Specification

(a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.

(b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.

(c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.

(d) The Names Of The Parties To A Joint Research Agreement: See 37 CFR 1.71(g).

(e) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.

(f) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:

(1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."

(2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."

(g) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.

(h) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.

(i) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.

(j) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).

(k) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).

(l) Sequence Listing, See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

Claim Objections

Claim 1 is objected to in the recitation of "the gene GSTA1" and "the gene WIR1a" which imply that there is only one GSTA1 gene and one WIR1a gene. It is unclear if there is only one GSTA1 gene and one WIR1a gene.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1, 3-18, and 21-32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a recombinant promoter comprising promoter sequence of SEQ ID NO: 1 and the intron sequence of SEQ ID NO: 2, a chimeric gene comprising said recombinant promoter operably linked to a coding sequence of interest, a method of transforming a plant with said chimeric gene, and a transgenic plant and progeny thereof comprising said recombinant promoter or chimeric gene, does not reasonably provide enablement for a promoter region comprising a promoter from the GSTA1 gene and an intron from WIR1a gene, or a functional part of SEQ ID NO: 3 or a sequence that hybridizes thereto under stringent conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to a promoter region having specificity for plant

epidermis, comprising a first sequence from the promoter of the gene GSTA 1 and a second sequence from the intron of the gene WIR1; a promoter region comprising a functional part of SEQ ID NO: 3 or a sequence that hybridizes thereto under stringent conditions; a chimeric gene comprising said promoter operably linked with a desired coding sequence, a method for generating transgenic plants with epidermis specific expression of a transgene by transforming the plants with a recombinant nucleic acid or chimeric gene comprising said promoter sequence, and transgenic plant and plant parts comprising said promoter. In contrast, the specification provides guidance for the a promoter sequence comprising SEQ ID NO: 1 and SEQ ID NO: 2, or the sequence of SEQ ID NO: 3, and a method of expressing a desired coding sequence in a transgenic plant under said promoter sequence for epidermis specific expression.

The specification does not teach all promoters from the GSTA1 genes and all introns from WIR1a genes. No guidance has been provided for the specific isolation of GSTA1 promoters and WIR1 introns. The specification does not teach a single variant of SEQ ID NO: 3 having a functional part of SEQ ID NO: 3 or sequences that hybridize thereto under stringent conditions and capable of directing epidermis specific expression of a desired coding sequence. The scope of the claimed promoter sequence having a functional part of SEQ ID NO: 3 or sequences that hybridize thereto encompasses sequences with one or more nucleotide modifications including internal deletions and substitutions. However, the specification does not provide guidance regarding internal deletion analysis of SEQ ID NO: 3 to show which nucleotides would tolerate modifications while retaining epidermis specific expression. No guidance has

been provided for any modifications to SEQ ID NO: 3 that resulted in a functional part or hybridizing sequences thereto and still directing epidermis-specific expression of a desired coding sequence. No regions necessary for promoter activity have been disclosed or evaluated for these sequences. Applicant has not provided guidance as to what modifications would allow the disclosed sequences to retain their regulatory activity, so that heterologous genes can be expressed to provide the desired trait in transgenic plants. In addition, No transgenic plant with altered gene expression or altered phenotype using said functional part or hybridizing sequence of SEQ ID NO: 3 have been disclosed.

The state of the art teaches unpredictability inherent in promoters to function either constitutively or tissue-specifically when one or more nucleotide bases of the promoter are modified. For example, Kim et al (Plant Molecular Biology, 1994 vol. 24, pp. 105-117) teach the extreme sensitivity of promoter regions to single base pair changes, the absolute requirement for as few as 3 to 6 nucleotides for promoter function, and the failure of a promoter to function either constitutively or specifically when lacking oligonucleotide regions approximately 100 bp upstream of the transcription start site (page 106, paragraph bridging the columns; paragraph bridging pages 107 and 108; page 110, paragraph bridging the columns).

While Applicant is not required to exemplify each and every claimed embodiment, specific guidance is required with respect to which region of the disclosed sequence can be modified so that the epidermis-specific regulatory activity is retained. Absent such guidance, one skilled in the art would not be able to make and use the

promoter sequences as broadly claimed to provide epidermis specific expression of transgenes in transgenic plants, without undue experimentation.

Therefore, given the lack of guidance as discussed supra; the unpredictability inherent in the function of a promoter when lacking specific regions necessary for regulatory activity, the breadth of the claims; and state of the art, the claimed invention is not enabled.

See *Amgen Inc. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1027 (Fed. Cir. 1991), where it is taught that the disclosure of few sequences did not enable claims broadly drawn to any analog thereof.

Written Description

Claims 1, 3-18, and 21-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a promoter region comprising a promoter from the GSTA1 and an intron from WIR1a, a promoter sequence comprising a functional part of SEQ ID NO: 3 and sequences that hybridize thereto under stringency conditions and that direct epidermis expression of a desired coding sequence in a transgenic plant; methods of using said promoter sequences and transgenic plant and parts thereof comprising said promoter sequences are also claimed. In contrast, Applicant describes a method that employs the promoter sequences of SEQ ID NO: 3 or 1 and 2.

These are genus claims.

See University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (Fed. Cir. 1997) where it states "A description of a genus of cDNA may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to all members of the genus, which features constitute a substantial portion of the genus. See also where the court teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from the organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

Applicant has not described the composition and structure of a functional part of any size and length from SEQ ID NO: 3 or hybridizing sequences thereof having the desired promoter activity. There is no known correlation between structure and function of plant epidermis-specific promoters. Therefore, a substantial variation in structures and function are expected among said non-described functional parts and hybridizing sequences. In addition, promoter sequence from the GSTA1 gene and an intron from the WIR1a are not adequately described because the abbreviations "GSTA1" and "WIR1a" do not imply any structural-functional property which would distinguish the claimed promoter and intron from other promoters and introns, respectively. Therefore, given this lack of written description, it is unclear if Applicant was in possession of the invention as broadly claimed. Since Applicant has not described functional parts and

hybridizing sequences, methods that employ said functional parts and hybridizing sequences are similarly not described. Therefore, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that one skilled in the art would recognize that Applicants are in possession of the invention as broadly claimed.

Accordingly, in view of all the above, the claimed invention lacks adequate written description as required under the current written description guidelines.

Remarks

Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MEDINA A. IBRAHIM whose telephone number is (571)272-0797. The examiner can normally be reached on M-TH (8:30-5:30) and every other Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Grunberg Anne Marie can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MAI
4/27/08

/Medina A Ibrahim/
Primary Examiner, Art Unit 1638